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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,421	12/09/2003	Mohan Krishnan	279.650US1	3925
21186	7590	06/20/2005	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402-0938			SMITH, TERRI L	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/731,421

Applicant(s)

KRISHNAN ET AL.

Examiner

Terri L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 8 and 19-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 9-12 and 14-18 is/are rejected.
- 7) ☒ Claim(s) 6, 7 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the invention of Group I, claims 1–20, and election of species of Embodiment I, the lead being treated so as to form a pseudo-intimal layer, in the reply filed on May 25, 2005 is acknowledged. Applicant believes that claims 1–20 read thereon, with at least claims 1 and 17 being generic to all species.

However, after receipt of Applicant's election, Examiner realized that the species of Embodiment I had inadvertently been named as a pseudo-layer rather than a coating including microspheres as it should have been. Examiner telephoned Peter Maki on Monday, June 13, 2005, explained the error and the correction, and Peter Maki elected Embodiment I as corrected, without traverse. Claims 1, 5–7, and 9–18 read on Group I and Embodiment I with at least claims 1 and 17 being generic to all species.

2. Claims 2–4, 8, and 19–23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 25, 2005.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Fig. 4, reference character 40. Examiner believes that reference character 40 should be reference character 410 as per the description "outer surface 410" in the specification on page 5, line 13. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the

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reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office Action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the applicant will be notified and informed of any required corrective action in the next Office Action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. Claims 6–7, 10, and 15–16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 6, the phrase "a coating" (line 1) is vague. Is this the same coating used in claim 5 on which claim 6 depends?

In claims 10 and 16, "a pulse generator" (line 1 in each claim) is inferentially included and it cannot be determined if the pulse generator is being positively recited or functionally recited. To positively claim the element, it is suggested to first positively recite the element. Otherwise, functional language such as "for" or "adapted to be" should be used.

In claim 15, "non-thrombogenic" (lines 1–2) is vague. It does not limit claim 11 since nothing is being added.

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Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 9, and 17 are rejected under 35 U.S.C. 102(b) as being anticipate by Vachon, U.S. Patent 5,861,023.

Vachon discloses a lead body extending from a proximal end to a distal end; and an electrode coupled to a lead body (Fig. 1); a lead body and an electrode each have an outer surface adapted to passively prevent and means for passively preventing formation of clots on outer surfaces (column 1, lines 9–12; column 4, lines 13–21); an outer surface of a lead does not include any active coatings which elute from the surface to minimize clotting (Figs. 1–2; column 5, lines 28–31).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vachon and in view of MacGregor, U.S. Patent 4,280,514.

Vachon does not disclose an outer surface of an electrode includes a textured coating or surface. However, MacGregor discloses an outer surface of an electrode includes a textured coating or surface (Fig. 3; column 2, lines 21–28) to render the surface resistant to the formation of blood clots (column 1, lines 41–42).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Vachon to include an outer surface of an electrode includes a textured coating or surface, as taught by MacGregor, to render the surface resistant to the formation of blood clots (column 1, lines 41–42).

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vachon and in view of Alt et al., U.S. Patent 6,370,427.

Vachon does not disclose a lead is coupled to a pulse generator and is adapted for delivering cardiac resynchronization therapy. However, Alt discloses a lead is coupled to a pulse generator (Fig. 1) to provide bi-ventricular therapy to the patient's heart in response to sensing applicable dysrhythmias (column 1, lines 8–10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Vachon to include a lead is coupled to a pulse generator, as taught by Alt, to provide bi-ventricular therapy to the patient's heart in response to sensing applicable dysrhythmias (column 1, lines 8–10).

10. Claims 1, 5, 11–12, and 14–17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al., U.S. Patent 6,574,512, and in view of Mar et al., U.S. Patent 5,411,544.

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Zhang discloses a lead body extending from a proximal end to a distal end, an electrode coupled to a lead body, an outer surface of a lead does not include any active coatings which elute from the surface to minimize clotting and is inherently non-thrombogenic, and is coupled to a pulse generator (Figs. 1 and 17; column 6, lines 4–5) and an electrode has an outer surface adapted to passively prevent and means for passively preventing formation of clots on the outer surface and includes an outer textured surface including microspheres and adapted to trap blood cells within a textured surface to form a layer of blood cells on the electrode surface (Fig. 1, element 134; column 5, lines 59–63). However, Zhang does not disclose a lead body has an outer surface adapted to passively prevent and means for passively preventing formation of clots on the outer surface and has a textured outer surface. Mar, on the other hand, discloses a lead body has an outer surface adapted to passively prevent and means for passively preventing formation of clots on the outer surface and has a textured outer surface (Fig. 1) to promote tissue adhesion (column 3, line 53) that renders the surface resistant to the formation of blood clots.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Zhang to include a lead body has an outer surface adapted to passively prevent and means for passively preventing formation of clots on the outer surface and has a textured outer surface, as taught by Mar, to promote tissue adhesion (column 3, line 53) that renders the surface resistant to the formation of blood clots.

11. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang and Mar as applied to claim 11 above, and further in view of Vachon, U.S. Patent 5,861,023.

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Zhang and Mar do not disclose a lead outer surface is inherently non-thrombogenic.

However, Vachon discloses a lead outer surface is inherently non-thrombogenic (column 5, lines 28–31) to inhibit the formation of blood clots.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the inventions of Zhang and Mar to include a lead outer surface is inherently non-thrombogenic, as taught by Vachon, to inhibit the formation of blood clots.

12. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vachon as applied to claim 17 above, and in view of Zhang et al., U.S. Patent 6,574,512.

Vachon does not disclose a microsphere outer surface coating on at least a portion of an electrode. However, Zhang discloses a microsphere outer surface coating on at least a portion of an electrode (Fig. 1, element 134) to make the surface more porous to prevent the formation of blood clots.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Vachon to include a microsphere outer surface coating on at least a portion of an electrode, as taught by Zhang, to make the surface more porous to prevent the formation of blood clots.

Allowable Subject Matter

13. Claims 6–7 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..


If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


TLS

June 16, 2005

16 June 2005


GEORGE R. EVANISKO
PRIMARY EXAMINER

6/16/2005